

# United States Patent and Trademark Office



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/635,117	08/06/2003	Daniel E. Couto	GTC-207 2070  EXAMINER		
31904	7590 02/16/2006				
	GTC BIOTHERAPEUTICS, INC.			MONDESI, ROBERT B	
	175 CROSSING BOULEVARD, SUITE 410 FRAMINGHAM, MA 01702		ART UNIT	PAPER NUMBER	
	,		1653		
			DATE MAILED: 02/16/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Summer	10/635,117	COUTO ET AL.				
Office Action Summary	Examiner	Art Unit				
	Robert B. Mondesi	1653				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	TE OF THIS COMMUNICATION 6(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 19 De	ecember 2005					
•—	action is non-final.					
,_	· —					
closed in accordance with the practice under E	· ·					
Disposition of Claims						
4)⊠ Claim(s) <u>1-6 and 10-72</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-6 and 10-72</u> is/are rejected.						
7) Claim(s) is/are objected to.	· ··					
8) Claim(s) are subject to restriction and/o	r election requirement.					
	,					
Application Papers						
9) The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:						
1. Certified copies of the priority document	s have been received.					
2. Certified copies of the priority document	s have been received in Applicat	ion No				
3. Copies of the certified copies of the prior	rity documents have been receiv	ed in this National Stage				
application from the International Bureau						
* See the attached detailed Office action for a list	of the certified copies not receiv	ed.				
	·					
Attachment(s)						
1) Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  A) Interview Summary (PTO-413)  Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  5) Notice of Informal Patent Application (PTO-152)						
Paper No(s)/Mail Date	6) Other:					
0 P. A. A. T. A. A. Office						

#### **DETAILED ACTION**

This Office action is in response to the amendment filed December 19, 2005.

Claims 1-6 and 10-72 are presently pending and under examination.

#### Withdrawal of Objections and Rejections

The objections and rejections not explicitly restated below are withdrawn.

### Maintenance of rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### Claim Rejections - 35 USC § 112

Claims 1-6 and 10-72 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 22, 70 and 71 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

## Claim Rejections - 35 USC § 102

Claims 1-7, 9-10, 14-19, 20-54, 59-61 and 72 remain rejected under 35 U.S.C. 102(b) as being anticipated by van Reis et al.

## Claim Rejections - 35 USC § 103

Claims 12-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over van Reis et al. in view of Kunihau et al.

Page 3

The above rejections were explained in previous Office actions mailed November 18, 2005, December 16, 2004 and April 15, 2004.

## Response to applicant's arguments

In response to the rejection of **claims 1-6 and 10-72** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, the applicants assert that they have consistently taken the position that the teachings and <u>enablement</u> provided by the specification are more than adequate to generate the current claims. The applicants assert further that the standard for <u>enablement</u>, as proclaimed in the first paragraph of 35 U.S.C. 112 is that, "(T)he specification shall contain a written description of the invention, and the manner and process of making and using it in such full, clear, concise and exact terms as to <u>enable</u> any person skilled in the art to which it pertains, or with which it is most nearly connected to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Applicants' arguments have not been found persuasive. The rejection of the claims is under 35 U.S.C, 112 first paragraph due to a <u>new matter</u> situation. As previously indicated and explained in the Office action mailed November 18, 2005, the applicants have amended the claims to include limitations that do not have support in accordance with the requirements of written description under 35 U.S.C. 112, first

Application/Control Number: 10/635,117

Art Unit: 1653

paragraph. Applicants' arguments are directed towards U.S.C, 112 first paragraph, lack of enablement, and are not germane to the present rejection for <u>new matter</u>.

Applicants have <u>not</u> responded to the rejection of the **claims 22, 70 and 71** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to the rejection of **claims 1-7, 9-10, 14-19, 20-54, 59-61 and 71** under 35 U.S.C. 102(b) as being anticipated by van Reis et al. and **Claims 12-13** under 35 U.S.C. 103(a) as being unpatentable over van Reis et al. in view of Kunihau et al., the applicants assert that the Declaration attached hereto explicates not just the minor differences separating van Reis from the current claims but demonstrates why the two publications are very distinct and separate methodologies approaching TFF.

Applicants' arguments have not been found persuasive. In the Declaration filed December 19, 2005, Mr. Mark A. Perreault asserts that after a review of the citations provided by the Examiner against the current claims it is my opinion that substantial differences remain. The difficulty in seeing this was primarily caused by the way in which the data was presented. When van Reis is plotted on the same data curves as the current invention it is clear that van Reis "operates" in a different fashion from the current invention and its corresponding claims. This provides for the foundation for saying that van Reis and the current invention are definitively different. Typical data along this line is presented below. When compared to van Reis data it clearly

demonstrates the difference between the existing prior art and the current invention.

This is true of van Reis et al., Kondo et al., and Kunihau et al., as presented to

Applicants by the Examiner in this case.

Mr. Perreault asserts further that in Diagram # A, some of the terms for Claim # 1 of the referenced patent application are defined. With in a TMP vs. Flux graph, two major lines are drawn: the Water Flux (J water) and the Product Flux (J feed stream). The Product Flux curve defines a maximum product flux (Jmax), which intersects the water flux line. At this point a bisecting line is drawn from the intersection of the two lines (J water and J max) to the Product Flux curve. The point at which the bisect intersects the J feed stream curve is defined as the transition point flux (J tp). A line is dropped directly down to the X axis to define the transition point transmembrane pressure (TMP tp).

Mr. Perreault also asserts that In the Van Reis patent # 5,256,294, the zone that is in Claim #1 is the area in light blue in Diagram #B bound by 100% to 5% of the JT and the TMP to vertical line. The current invention rests its amended claims in the area of Diagram #B in light green bound by a Flux greater than 100% of the JT and the TMP to vertical line.

It is also important to point out that Mr. Perreault, on page 7, lines 6-10, has stated on the record that the TMP was found to be optimal at approximately about 15psig for the process described and has been presented during the prosecution of the present application and this optimal TMP of 15psig, is higher than the transition point pressure of 2.5psig supported by table D.

Application/Control Number: 10/635,117 Page 6

Art Unit: 1653

In response, the examiner would like to restate that the arguments have not been found persuasive. The Diagrams that Mr. Perreault refers to for his arguments, Diagram A and Diagram B are cartoons (clarification by the examiner: The phrase cartoon is not being used as a negative connotation but rather to indicate that he Diagrams/drawings are not supported by any numerical values!) and lack the ability to support an argument with regards to the optimal operating conditions. These Diagrams have no numerical bases what so ever, there is no way for a person skill in the art to know what psig value corresponds to 100% of transition point flux. Therefore it is not possible to determine the difference between the method of the present application and the method taught by Van Reis et al. by simply viewing these diagrams.

However, as mentioned above the Mr. Perreault, in a different section of the Declaration, filed December 19, 2005, has indicated on the record that the desired/optimal transmembrane pressure corresponds to 15psigs.

Van Reis et al. teach that the operating transmembrane pressure of the method of the invention can be 15 psigs. In fact Van Reis et al., in Fig. 6 have taught that the TMP may be as high as 25psig. So clearly, the reference, Van Reis et al. teaches a transmembrane pressure that is envisioned by the method of the present application.

#### Conclusion

No claims are allowed

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1653

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B. Mondesi Patent Examiner Group 1653

02-13-05

JON WEBER
SUPERVISORY PATENT EXAMINER